REMARKS

In the Official Action of April 7, 2008, which the Examiner made Final, the Examiner: (a) rejected independent Claims 1 and 33, as well as many dependent claims, under 35 U.S.C. 102 and also under 35 U.S.C. 103, relying on newly–cited references; (b) objected to Claims 24–32 under 37 CFR 1.75(c) as being in improper form; and (c) maintained the objection to the drawings under 37 CFR .83(a).

First, applicant submits that making the action Final was clearly premature. Thus, although independent method Claim 33 was not amended in any manner in the previous response, the Examiner cited completely new references and new grounds of rejection of that claim. Clearly, therefore, there was no justification for making the action Final, particularly with respect to independent method Claim 33, and thereby deny the applicant an opportunity to address the new references and the new grounds of rejections.

Moreover, the Final Action of April 7, 2008 objected, for the first time, to Claims 24–32 under 37 CFR 1.75(c), even though no amendments whatsoever had been made to those claims in the previous Official Action. Accordingly, making the action Final thus also denied applicant the opportunity to address this new grounds of objection.

If the Final Action is not withdrawn, as requested above, applicant will have no alternative but to file an Appeal. However, applicant strongly feels that if the Remarks, as set forth below, with respect to all the grounds of rejection and objection are carefully considered by the Examiner, particularly in the light of the amendments proposed for Claims 11 and 24 a costly and time–consuming Appeal can be avoided.

Re: The Drawings

The drawings were objected to under 37 CFR 1.83(a) as not disclosing the construction defined in Claim 11. The same objection was made in the previous action and in reply, applicant pointed out the following (Page 15 of the Remarks):

> "It is submitted, however, that this feature is now clearly shown in the drawings, and therefore no drawing corrections are needed.
>
> For example, we refer to the paragraph of Page 10, lines 12–15, particularly the following passage:
>
> > 'The surface of base 11 facing the pressure applicator 12 and sensor 13, brought into contact with the subject's skin, includes an adhesive layer 14 for adhering the base to the subject's skin at the measurement site.'
>
> The adhesive layer is clearly seen at 14 in Figs. 1b, 1c, and at 24, 34, 44, 54 and 84 in many of the other figures of the drawings, and it is submitted that the above–quoted passage describing Figs. 1b, 1c, and the corresponding pages describing 24, 34, 44, 54, 84 clearly support the language used in Claim 11, and therefore no drawing correction is necessary."

In reply to the foregoing, the Examiner comments (the bridging paragraphs of Pages 20–21) as follows:

> "As to the pending drawing objection, the applicant submitted that the feature is clearly shown in the drawings and refers to the paragraph of p.10, line 12–15 and figures 1b and 1c for support. While the identified paragraph states that the surface of base 11 faces the pressure applicator 12 and sensor 13 and the surface includes an adhesive layer 14, none of the figures actually show the adhesive layer 'facing' the pressure applicator or the sensor. Instead, the figures show the adhesive layer 14 facing either upwards or downwards, wherein the adhesive layer would have to facing inward in order to be considered 'facing' the pressure applicator or sensor. Therefore, the objection to the drawings stand. (Emphasis added).

However, the Examiner's comments as set forth above are not based on a reasonable interpretation of the clear language in Claim 11. The clear meaning of Claim 11 is not that the adhesive layer (14) faces the pressure applicator and the sensor

(13), but rather that the adhesive layer is on the face of the base 11 facing the pressure applicator and sensor; that is, the adhesive layer is on the inner face of the base as distinguished from its outer face. Since this is clearly shown in Fig. 1b, and many other figures of the drawings, it is submitted that the features set forth in previous Claim 11 are clearly illustrated in the drawings, and therefore the objection under 37 CFR 1.82(a) should be withdrawn.

Nevertheless, to avoid any question, applicant proposes to amend Claim 11 as set forth above so that there is clearly no question but that the feature as so defined is clearly illustrated in the drawings.

Re: Claim Objections

As noted above, Claims 24–32 were objected to, for the first time, under 37 CFR 1.75(c) as being in improper form as failing to comply with MPEP 608.01(n). Since this objection was raised for the first time, as indicated above, this is the first opportunity applicant has had to address it.

First, it is to be noted that the purpose of 37 CFR 1.75(c) is to better assure compliance with the requirement of clarity and definiteness under 35 U.S.C. 112, second paragraph, so that the "metes and bounds" of the claim will be clear and definite. To meet the Examiner's objection to Claims 24–32, this would mean that Claim 24 would have to be amended as set forth in amended Claim 24 appearing above. The combination of features defined in previous Claim 24 are exactly the same as the combination of features defined in the proposed amended Claim 24. If the Examiner considers which Claim is clearer and more definite as to the "metes and bounds" of protection defined by the claim, there is no question in applicant's mind that the conclusion will be that

previous Claim 24 is clearer and more definite than the proposed amended Claim 24. To conclude otherwise would be to "elevate form over substance"; that is, to ignore the substantive reason for a formal technicality. In this case, the substantive reason for MPEP 608.01(n) is to better assure compliance with the requirements of clarity of definiteness of 35 U.S.C. 112, second paragraph.

In this respect, it is to be noted that almost all the examples of improper multiple dependent claims set forth in MPEP 608.01(n) involve multiple dependent claims with respect to a single feature, and that the only example of improper multiple claims involving different features (Section 3) is one where multiple claims are involved in one of the two features, whereas the other feature involves a single dependent claim. In the latter example involving two different features, there is indeed a high element of indefiniteness because of the various permutations and combinations obtainable with multiple claims. In the present case, however, wherein a single dependent Claim is involved in each of two different features, there is no such element of indefiniteness.

In any event, as indicated above, Claim 24 as proposed to be amended, is identical in scope and meaning as Claim 24 objected to, and therefore applicant would have no objections to including the proposed amended Claim 24 to avoid the "technical informality" referred to by the Examiner in MPEP 608.012(n).

Re: Rejection Under 35 U.S.C. 102

The Final Action of April 7, 2008 set forth two rejections of independent article Claim 1 and independent method Claim 33, together with many of their respective dependent claims, as unpatentable over Archibald et al U.S. Patent 6,132,382, and also as unpatentable over Moses U.S. Patent 5,368,039. Applicant submits, however, that this

application of 35 U.S.C. 102 in both of these rejections is inconsistent with the many holding involving the propriety of a 35 U.S.C. 102 rejection.

See for example, the following quotation from American Permahedge Inc. v. Barcana, Inc. 32 USPQ2d 1901 (at Pages 1807–1808):

> "Prior art anticipates an invention, rendering it invalid, pursuant to 35 U.S.C. 102, if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patented product. Scripps Clinic & Research Found v. Genentech, Inc., 927 F.2d 1565, 1576 [18 USPQ2d 1001] (Fed.Circ.1991); Carella v. Starlight Archery & Pro Line Co., 804 F.2d at 138. 'There must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention.' Scripps Clinic & Research Found v. Genentech, Inc., 927 Fig. 2d at 1576; see also E.I. Du Pont Nemours & Co. v. Polaroid Graphics Imaging, Inc., 706 Fig. Supp. 1135, 1142 [10 USPQ2d 1579] (D. Del 1989), aff'd, 887 F.2d 1095 [13 USPQ2d 1731] (Fed. Cir. 1989) ('all of the same elements [must be] found in exactly the same situation and united in the same way ... in a single prior art reference') (quoting Perkin Elmer Corp. v. Computervision, Corp., 732 F.2d 888, 894 [221 USPQ 669] (Fed. Cir. 1984). Thus, any degree of physical difference between the patented production and the prior art, no matter how slight, defeats the Claim of anticipation. E.I. Du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc., 706 F.Supp. At 1142"

The features included in Claim 1 clearly distinguish over the cited references in many respects. For example:

Archibald et al 6,132,382 relates to a hand held device which is applied to a body surface, in which the source of the applied pressure is the pressure brought to bear on the patient's body due to the operator's pressing the device on the patient's body. In the absence of operator applied pressure there would be no pressure generated on the patient's body.

In contrast, the pressure applicator referred to in present Claim 1 generates its own pressure, independently of an external source. Specifically, claim 1 recites "said

pressure applicator being designed to apply to said measurement site, when the base is applied thereto, a static pressure...."

In the case of Moses 5,368,039, and likewise, in the case of Ogura et al 6,332,869, the actual application of pressure is dependent on the use of an inflatable pressure cuff which by definition encircles a body part, and is thus fundamentally different from the devices described in the present application in which the pressure field is

> "configured to be applied to a relatively restricted area of the subject's skin, to apply said static pressure to said relatively restricted area , which area does not completely encircle the body part at said measurement site, said pressure applicator occupying a relatively small fraction of the surface perimeter of the respective body part at said measurement site,....."

It is well known that a pressurized cuff applied around a limb actually induces venous pooling of blood because it blocks the outflow of venous blood and thereby causes the veins in the distal part of the limb to become distended, and thus completely defeats the stated purposes of

> "..... being configured to substantially prevent venous distention and blood pooling at said measurement site by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site ...."

The Examiner apparently concedes that there are differences between the claimed invention and the reference disclosures, since the Examiner supports this rejection with the following comment (Page 5 of the Official Action):

> "The applicants should note that the language 'to thereby permit free venous drainage from the measurement site via a wide region of unrestricted passageways surrounding the measurement site' is merely '<u>results language</u>' describing the results of the pressure applicator applying the results of the pressure applicator applying the static structure as described. <u>This results language cannot be relied upon to define over the prior art</u>, since Archibald teaches all of the claimed structural features

> and their recited relationships. It is further noted that, since Archibald is configured to apply the static structure as claimed, if Archibald does not achieve the recited results, then the applicants have omitted an essential feature of the claimed invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph)." (Emphasis added)

The above quotation by the Examiner, involving what the Examiner considers to be "merely results language" appears at the end of independent Claim 1. However, it is to be noted that this quoted recitation from independent Claim 1 is preceded by many recitations of structural features to support this "result language", including the following:

(a) anti–pressure applicator applies a static pressure (third paragraph, Claim 1);

(b) the "static pressure" is of a sufficient magnitude to partially to unload the wall tension of, but not to occlude, the arteries at the measurement site; (first part of fourth paragraph)

(c) that the pressure applicator (last part of fourth paragraph, Claim 1

> "configured to substantially prevent venous distention and blood pooling at said measurement site by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to said measurement site through tissues surrounding said measurement site;"

(d) and finally, that the probe is (first part of last paragraph, Claim 1)

> "configured to be applied to a relatively restricted area of the subject's skin, to apply said static pressure to said relatively restricted area , which area does not completely encircle the body part at said measurement site, said pressure applicator occupying a relatively small fraction of the surface perimeter of the respective body part at said measurement site, to thereby permit free venous – – – "

In support of the Examiner's holding, the Examiner referred to MPEP 2173.054(g) regarding functional limitations. But the Examiner apparently overlooked the fact that this section of the MPEP expressly states:

> "A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional langue does not, in and of itself, render a Claim improper. *In re Swinehart*, F.2d 210, 169 USPQ 226 (CCPA 1971).
>
> A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element ingredient or step."

This section of the MPEP also sets forth a number of examples where functional limitations can be used, and are frequently are used, to distinguish over the prior art.

It is submitted, therefore, after MPEP 2173.05(g) is properly considered, it is clear that the above–discussed recitations appearing in the independent Claim 1 do not constitute merely "results language" not supported by structure, but rather structural features (although broadly recited) which clearly distinguish Claim 1 over the cited reference.

The same comments as set forth above with respect to apparatus Claim 1 apply with equal force with respect to method Claim 33 which includes apparatus Claim 1.

The foregoing comments also apply with respect to the second rejection under 35 U.S.C. 102, namely as unpatentable over Moses U.S. Patent 5,36,039 since the Examiner repeated the same language as set forth above also with respect to this rejection.

Re: Rejection under 35 U.S.C. 103

The Examiner also rejected independent apparatus Claim 1 and method Claim 33 under 35 U.S.C. 103(a) as being unpatentable over two groups of references, namely

(a) Ogura et al U.S. Patent 6,332,869 in view of Moses; and (b) Bobo U.S. Patent 5,230,342 in view of Sasaki et al U.S. Patent 4,896,676.

It is submitted that also in these rejections, the Examiner misapplied 35 U.S.C. 103 as interpreted in many prior Court decisions. See for example National Tractor Pullers Assn., Inc. v. Watkins 205 USPQ 892 wherein the Court stated (on Page 911):

> "The test of obviousness under 35 U.S.C. 103 is not whether a prior art device could be modified into something resembling the applicant's structure, but the proper test is whether, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art, given the teachings of the prior art, to make the invention. Graham v. John Deere, 383 US 1.148 USPQ 459 (1965). In considering the prior art, prior patents are references only for what they clearly disclose or suggest and it is not proper to modify their structure in a manner which is not suggested by prior art. In re Randol and Redford, 425 F.2d 1286, 165 USPQ 586 (CCPA 1970)"

It is submitted that combining the references, as suggested by the Examiner in both rejections of the claims under 35 U.S.C. 103, would not result in the combination of features set forth in either of Claims 1 and 33.

In the first rejection, Moses fails as an anticipation for the same reasons as discussed above under 35 U.S.C. 102; and in the second rejection, the Examiner also refers to the above–quotation of the Examiner with respect to "merely results language" discussing the Bobo primary reference.

Further, in noting that Bobo relates to an oscillometric method of blood pressure, the Examiner comments as follows with respect to the recitation in Claim 1 that the pressure applicator applies "a static pressure" (first full paragraph, Page 15):

> "The applicant should note that the language 'for applying a static pressure' on lines 6–7 of Claim 1 and 'designed to apply to said measurement site, when the base is applied thereto, a static pressure ...' on lines 11–18 of Claim 1, is merely 'intended use' language, which cannot

> be relied upon to define over the prior art, since Bobo, Jr. as modified, teaches all of the structural limitations of the claims and their recited relationships. The pressure applicator is certainly capable of being used to apply a static pressure as claimed."

Moreover, when the prior decisions on the propriety of combining references with respect to an obviousness rejection under 35 U.S.C. 103 are taken into consideration, it will be seen that the true test is not what a reference is "capable" of doing, but rather what it renders obvious to do in the absence of Applicant's disclosure. In this case, it is submitted that, particularly since the Bobo reference relates to measuring blood pressure by the oscillometric method, it would not have suggested or rendered obvious to one skilled in the art to use a static pressure, as this would have defeated the purpose of the method described in Bobo.

In support of this rejection, the Examiner notes that the oscillometric method described in this patent is performed in steps, and concludes that in each step a "static" pressure is applied. Applicant submits, however, that even when such an oscillometric method is performed in steps, it is still a "variable pressure" method, namely a "stepped–variable" method, rather than a "continuously–variable" method, as in the conventional oscillometric method, and not a "static–pressure" method.

In the section titled "Response to Arguments" (starting Page 20) of the Official Action of April 7, 2008 the Examiner maintains that (a) merely intended use language cannot be relied upon to define over prior art; and (b) the pressure applicator, particularly in Bobo, "is certainly capable of being used to apply a static pressure as claimed". It is believed, however, that both of the above contentions by the Examiner have been clearly refuted in the extensive discussion above with respect to the propriety of a rejection under 35 U.S.C. 102, and also under 35 U.S.C. 103.

It is also to be noted that on page 22 of the section titled "Response to Arguments", the Examiner rejected the arguments that in the Bobo et al design, the bladder 18 and bladder backing 19, by virtue of being interposed between the adhesive pad 20 and the body surface, could generate an indeterminate local force at the tissue interface with elements 18 and 19 after the backing 20 was adhered to the patient's skin,

However, this indeterminate force could be generated even without the pressure bladder being pressurized at all, (i.e. a pressure of 0 torr in the bladder), since "the bladder extends out from the pad and back", and therefore when the pad 20 is adhered to the skin, the bladder 18 and bladder backing 19 must to some extent be forced to press on the body surface. The actual magnitude of such a force could not be known in advance, thus it could at least partially occlude the arteries, at least at some body surface locations.

> "The backing 19 insures that the bladder extends out from the pad and backing against the artery when it is pressurized. Also, in a preferred embodiment, it is initially molded or otherwise provided in a convex shape so as to act as a spring in urging the bladder against the patient's supraorbital artery." (column 3, lines 62–68)

The Examiner further states that "Furthermore, Bobo, Jr. discloses the pressure applicator being capable of applying a pressure between 0 **and 160 torr** (see entire document, especially col. 4, lines 9-30 of Bobo, Jr.)". However, it is to be noted that as clear from col. 4, lines 9–30, Bobo actually refers to the pressure within the bladder (18). As explained above, the pressure applicator could apply a different, (and unknown) pressure to that applied within the bladder.

Since Claim 1 recites ".....but not to occlude, the arteries at said measurement site....", it is submitted that this possibility is sufficient to distinguish Claim 1 over this reference, whether taken alone or in combination with the secondary reference.

Applicant has taken the trouble to make a very prompt and extensive response to the Final Action of April 7, 2008 in the hope that the expense and time consumption of filing an Appeal before the Board of Appeals can be avoided. If, however, the Examiner is still not convinced, it is requested that the Examiner withdraw the Final Rejection for reasons set forth above, so that the Applicant can consider whatever additional comments the Examiner wishes to make. If, however, the Examiner still maintains the Final Rejection, it is requested that the above proposed amendments be entered for purposes of appeal. If the Examiner, however, refuses to enter the above–proposed amendments, then Applicant intends to file an Appeal based on the application as finally rejected in the Final Action of April 7, 2008.

Since the application is under a Final, an early and favorable action is particularly solicited.

Respectfully submitted,

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